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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/440,829	CHENCHIK ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-23 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-23 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 24 March 2003 in which claims 1, 2, 8, 18 and 18 were amended; claims 36-38 were canceled; and a Declaration filed under 35 U.S.C. 1.132 by Dr. Alexander Munishkin was submitted. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 15 October 2002 are withdrawn in view of the amendments.

All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-3, 7-23 and 35 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 7, 10-16 and 18-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Linsley et al (U.S. Patent No. 6,271,002, filed 4 October 1999).

Regarding Claim 1, Linsley et al disclose an array comprising at least one pattern of probe spots stably attached to sites on the surface of a glass support wherein each probe spot comprises probes that range in length from 60 to about 120 nucleotides (Column 22, lines 5-11 and Column 25, lines 32-33).

Regarding Claim 2, Linsley et al disclose the array wherein two or more different targets hybridize to different probe spots (Column 22, lines 31-35).

Regarding Claim 3, Linsley et al disclose the array wherein each spot hybridizes to a different target (Column 23, lines 55-60).

Regarding Claim 7, Linsley et al disclose the array wherein the probes are covalently attached i.e. synthesized onto the support using photolithography (Column 25, lines 59-67).

Regarding Claim 10, Linsley et al disclose the array wherein the spots do not exceed a density of about 1000/cm^2 (Column 22, lines 43-47).

Regarding Claim 11, Linsley et al disclose the array wherein the spots do not exceed a density of about 400/cm^2 (Column 22, lines 43-47).

Regarding Claim 12, Linsley et al disclose the array wherein the spot range from about 50 to 50,000 in number (Column 22, lines 11-35).

Regarding Claim 13, Linsley et al disclose the array wherein the spot range from about 50 to 10,000 in number (Column 22, lines 11-35).

Regarding Claim 14, Linsley et al disclose an array comprising at least one pattern of probe spots covalently attached i.e. via photolithography (Column 25, lines 59-67) to sites on the surface of a support wherein each probe spot comprises probes that range in length from 60 to about 120 nucleotides (Column 22, lines 5-11 and Column 25, lines 32-33).

Regarding Claim 15, Linsley et al disclose the array wherein the array comprises ten or more different spots each of which hybridize to a different target (Column 22, lines 31-35)

Regarding Claim 16, Linsley et al disclose the array wherein each spot hybridizes to a different target (Column 23, lines 55-60).

Regarding Claim 18, Linsley et al disclose the array wherein the oligonucleotides range from about 65 to 90 nucleotides in length (Column 22, lines 5-9).

Regarding Claim 19, Linsley et al disclose the array wherein the spots do not exceed a density of about 1000/cm^2 (Column 22, lines 43-47).

Regarding Claim 20, Linsley et al disclose the array wherein the spots do not exceed a density of about 400/cm^2 (Column 22, lines 43-47).

Regarding Claim 21, Linsley et al disclose the array wherein the spot range from about 50 to 50,000 in number (Column 22, lines 11-35).

Regarding Claim 22, Linsley et al disclose the array wherein the spot range from about 50 to 10,000 in number (Column 22, lines 11-35).

Regarding Claim 23, Linsley et al disclose an array comprising at least one pattern of probe spots that does not exceed about 400 spots /cm^2 covalently attached i.e. via photolithography (Column 25, lines 59-67) to sites on the surface of a glass support wherein each probe spot comprises probes that range in length from 65 to about 90 nucleotides (Column 22, lines 1-11 and Column 25, lines 32-33).

4. Claims 1, 7, 8, 10, 11, 14, 18-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et (U.S. Patent No. 5,688,642, issued 18 November 1997).

Regarding Claim 1, Chrisey et al disclose an array comprising at least one pattern of probe spots stably attached to sites on the surface of a glass support (Column 7, lines 21-27) wherein each probe spot comprises probes that range in length from 60 to about 120 nucleotides (Column 8, lines 46-47 and Claim 14).

Regarding Claim 7, Chrisey et al disclose the array wherein the probes are covalently attached (Example 9, Column 14, line 46-Column 15, line 37).

Regarding Claim 8, Chrisey et al disclose the array wherein the probes are crosslinked to the solid support (Example 9, Column 14, line 46-Column 15, line 37).

Regarding Claim 10, Chrisey et al disclose the array wherein the spots do not exceed a density of about 1000/cm^2 i.e. 100μ m x 100μ m features (Example 7, Column 13, line 60-Column 14, line 11).

Regarding Claim 11, Chrisey et al disclose the array wherein the spots do not exceed a density of about 400/cm^2 i.e. 100μ m x 100μ m features (Example 7, Column 13, line 60-Column 14, line 11).

Regarding Claim 14, Chrisey et al disclose an array comprising at least one pattern of probe spots covalently attached to sites on the surface of a support wherein each probe spot comprises probes that range in length from 60 to about 100 nucleotides (Column 8, lines 46-48 and Example 9, Column 14, line 50-Column 15, line 37).

Regarding Claim 18, Chrisey et al disclose the array wherein the oligonucleotides range from **about** 65 to 90 nucleotides in length (Column 8, lines 46-48 and Claim 14).

Regarding Claim 19, Chrisey et al disclose the array wherein the spots do not exceed a density of about 1000/cm^2 i.e. 100μ m x 100μ m features (Example 7, Column 13, line 60-Column 14, line 11).

Regarding Claim 20, Chrisey et al disclose the array wherein the spots do not exceed a density of about 400/cm^2 i.e. 100μ m x 100μ m features (Example 7, Column 13, line 60-Column 14, line 11).

Regarding Claim 23, Linsley et al disclose an array comprising at least one pattern of probe spots that does not exceed about 400 spots /cm^2 (Example 7, Column 13, line 60-Column 14, line 11).covalently attached to sites on the surface of a glass support (Column 7, lines 21-27) wherein each probe spot comprises probes that range in length from **about** 65 to

about 90 nucleotides (Column 8, lines 46-48 and Example 9, Column 14, line 50-Column 15, line 37).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al (U.S. Patent No. 6,037,127, filed 26 November 1997).

Regarding Claim 1, Ebersole et al disclose an array comprising at least one pattern of probe oligonucleotide spots stably attached to the surface of a solid glass support (Column 20, lines 1-7) wherein each probe spot comprises a probe composition made up of long oligonucleotide probes that range in length from 10 to 300 nucleotides (Column 13, lines 21-26) and they specifically teach oligonucleotide probes of 45-57 (Example 7, Column 33, line 25-Column 34, line 52). Ebersole et al do not specifically teach the probe range of 60 to about 120. However, The courts have stated where the claimed ranges "overlap or lie inside the ranges disclose by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are closed enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257,

191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP, 2144.05 I.). Therefore, the claimed ranges of 60-120 which lie inside the ranges of Ebersole et al are obvious in view of the teaching of Ebersole et al because one of ordinary skill in the art would have expected the 57-mer of Ebersole et al and the instantly claimed 60-mer to have similar functional properties.

Regarding Claim 2, Ebersole et al disclose the array wherein two or more different target nucleic acids hybridize to different probe spots in said pattern (Column 33, lines 36-45).

Regarding Claim 3, Ebersole et al disclose the array wherein each probe spot in said pattern hybridizes to a different target nucleic acid (Column 33, lines 36-45).

Regarding Claim 7, Ebersole et al disclose the array wherein each of said long probes are covalently attached to said surface of said substrate (Column 33, lines 30-35).

Regarding Claim 8, Ebersole et al disclose the array wherein each of said long probes is crosslinked to the surface of said support (Column 33, lines 30-35).

Regarding Claim 9, Ebersole et al disclose the array wherein each of said probes is crosslinked to the surface at at least two sites e.g. probe p3 is crosslinked on Capture Zone 1, strips A through G (Column 33, lines 36-45 and Fig. 12).

Regarding Claim 10, Ebersole disclose the array wherein the spots on the array do not exceed a density of about 1000/cm^2 (Column 19, lines 38-55 and Fig 12).

Regarding Claim 11, Ebersole disclose the array wherein the spots on the array do not exceed a density of about 400/cm^2 (Column 19, lines 38-55 and Fig 12).

Regarding Claims 12 and 13, Ebersole et al teach the array comprising at least one pattern of probe oligonucleotide spots stably attached to the surface of a solid support wherein each probe spot comprises a probe composition made up of long oligonucleotide probes that range in length from about 50 to 100 nucleotides (Example 7, Column 33, line 25-Column 34, line 52) wherein the number of spots is at least 21 (see Fig. 12) but they do not teach the

number of spots range from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13). However, the courts have stated that when a claimed device recites change in shape, size or dimension of a prior art device, the claimed device is not patentably distinct from the prior art device (531 F.2d at 1053, 189 USPQ at 148; In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Therefore, the claimed range of spots i.e. from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13) is not patentably distinct from the array of Ebersole et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array comprising 21 spots of Ebersole et al. useful for detecting multiple analytes in a sample and to increase the number of spots to 50 to thereby include 50 known analyte-specific nucleic acids for the expected benefit of providing an array useful for detecting multiple clinically important analytes.

Regarding Claim 14, Ebersole et al disclose an array comprising at least one pattern of probe oligonucleotide spots stably attached to the surface of a solid support wherein each probe spot comprises a probe composition made up of long oligonucleotide probes that range in length from **about** 60 to 100 nucleotides i.e. 45-57 (Column 13, lines 21-26 and Example 7, Column 33, line 25-Column 34, line 52).

Regarding Claim 15, Ebersole et al teach the array wherein two or more different target nucleic acids hybridize to different probe spots in said pattern (Column 33, lines 36-45) but they do not teach the array comprises ten or more different probe spots each of which hybridize to a different target. However, the courts have stated that when a claimed device recites change in shape, size or dimension of a prior art device, the claimed device is not patentably distinct from the prior art device (531 F.2d at 1053, 189 USPQ at 148; In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Therefore, the claimed number of different spots i.e. ten or more is not patentably distinct from the array of Ebersole et al. Additionally, it would have been obvious to

one of ordinary skill in the art at the time the claimed invention was made to modify the array comprising three different target-specific spots of Ebersole et al. useful for detecting multiple analytes in a sample and to increase the number of different spots to at least 10 to thereby include 10 known analyte-specific nucleic acids for the expected benefit of providing an array useful for detecting multiple clinically important analytes.

Regarding Claim 16, Ebersole et al teach the array wherein each probe spot in said pattern hybridizes to a different target (Column 33, lines 36-45).

Regarding Claim 17, Ebersole et al teach the array wherein two or more spots in said pattern hybridize to the same target (Column 33, lines 36-45).

Regarding Claim 18, Ebersole et al teach the array wherein the oligonucleotide probes that range in length from about 60 to 90 nucleotides i.e. 47-57 (Example 7, Column 33, line 25-Column 34, line 52) and they teach the probes range in size from 10 to 300 (Column 13, lines 21-26) which clearly suggests the claimed range of from about 65-90. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe length of Ebersole et al using routine experimentation based on the suggested probe lengths taught by Ebersole (i.e. 10 to 300; Column 13, lines 21-26) and to derive an optimal probe length (e.g. 65-90) for the expected benefits of maximizing probe function. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 19, Ebersole disclose the array wherein the spots on the array do not exceed a density of about 1000/cm^2 (Column 19, lines 38-55 and Fig 12).

Regarding Claim 20, Ebersole disclose the array wherein the spots on the array do not exceed a density of about 400/cm^2 (Column 19, lines 38-55 and Fig 12).

Regarding Claims 21 and 22, Ebersole et al teach the array comprising at least one pattern of probe oligonucleotide spots stably attached to the surface of a solid support wherein

each probe spot comprises a probe composition made up of long oligonucleotide probes that range in length from about 50 to 100 nucleotides (Example 7, Column 33, line 25-Column 34, line 52) wherein the number of spots is at least 21 (see Fig. 12) but they do not teach the number of spots range from about 50 to 50,000 (Claim 21) and from about 50 to 10,000 (Claim 22). However, the courts have stated that when a claimed device recites change in shape, size or dimension of a prior art device, the claimed device is not patentably distinct from the prior art device (531 F.2d at 1053, 189 USPQ at 148; In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Therefore, the claimed range of spots i.e. from about 50 to 50,000 (Claim 12) and from about 50 to 10,000 (Claim 13) is not patentably distinct from the array of Ebersole et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the array comprising 21 spots of Ebersole et al. useful for detecting multiple analytes in a sample and to increase the number of spots to 50 to thereby include 50 known analyte-specific nucleic acids for the expected benefit of providing an array useful for detecting multiple clinically important analytes.

Regarding Claim 23, Ebersole et al disclose an array comprising at least one pattern of probe oligonucleotide spots of a density that does not exceed about 400/cm^2 covalently attached to the surface of a solid glass support (Column 20, lines 1-7) wherein each probe spot comprises a probe composition made up of long oligonucleotide probes that range in length from **about** 65 to 90 nucleotides i.e. 45-57 (Example 7, Column 33, line 25-Column 34, line 52) and they teach the probes range in size from 10 to 300 (Column 13, lines 21-26) which clearly suggests the claimed range of from about 65-90. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe length of Ebersole et al using routine experimentation based on the suggested probe lengths taught by Ebersole (i.e. 10 to 300; Column 13, lines 21-26) and to derive an optimal probe length (e.g. 65-90) for the expected benefits of maximizing probe function. It is noted that *In re Aller*, 220 F.2d

454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al (U.S. Patent No. 6,037,127, filed 26 November 1997) in view of Stratagene (catalog, 1988. page 39).

Regarding Claim 35, Ebersole et al teach an array comprising at least one pattern of probe oligonucleotide spots stably attached to the surface of a solid glass support (Column 20, lines 1-7) wherein each probe spot comprises a probe composition made up of long oligonucleotide probes that range in length from about 50 to 100 nucleotides i.e. 45-57 (Example 7, Column 33, line 25-Column 34, line 52) but they do not teach the array in a kit. Stratagene catalog teaches a motivation to combine reagents into kit format (page 39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the array of Ebersole et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

Response to Arguments

8. Applicant relies on the Declaration by Alexander Munishkin to overcome the above obviousness rejection over the teaching of Ebersole.

9. The Declaration under 37 CFR 1.132 filed 24 March 2003 is insufficient to overcome the rejection of claims 1-23 and35 based upon Ebersole et al as set forth in the last Office action. Ebersole et al teach their probes range in length from 10 to 300 bases (Column 13, lines 21-26). Furthermore, they teach an embodiment wherein the probes are 57 nucleotides in length (Example 7, Column 33, line 25-Column 34, line 52).

The evidence provided in the Declaration illustrates an improved signal as the probe length increases from 40 to 100 nucleotides in length (Exhibit B) and improved signal of 80-mers compared to 200-700mers (Exhibit C). The claims are drawn to probe lengths of 60 to 120 and the prior art exemplifies 57mers. The Declaration does not provide evidence that the claimed 60-120 length provides an unexpectedly improved signal over the 57mer known in the art. As such, the Declaration does not provide sufficient evidence to illustrate unexpected results for the claimed probe lengths and to overcome the obviousness rejection in view of the teaching of Ebersole et al .

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 17, 2003